4/14/92

DATA EVALUATION REPORT

TREO SPF 15 Lotion

Study Type: Acute Inhalation Toxicity in Rats

Prepared for:

Health Effects Division
Office of Pesticide Programs
Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031-1207

Principal Reviewer	Jessica Kidwell	4/14/92
	Jessica Kidwell	Date
Independent Reviewer	John Liccione	4/14/92
	John Liccione	Date
QA/QC Manager	Sharon Segal	4/14/92
	Sharon Segal	Date

Contract Number: 68D10075
Work Assignment Number: 1-76
Clement Number: 91-243
Project Officer: James E. Scott

EPA Reviewer: Dr. J. Thomas McClintock
Reregistration Section, SACB, HED

Signature: J. Thomas McClintock
Date: 4/29/92

EPA Section Head: Dr. Albin Kocialski
Reregistration Section, SACB, HED

Signature: ABK
Date: 4/29/92

DATA EVALUATION REPORT

STUDY TYPE: Guideline series 81-3 and 152-12: Acute inhalation toxicity in rats

EPA IDENTIFICATION NUMBERS

Tox. Chem. Number: 21901
MRID Number: 421513-06

TEST MATERIAL: TREO SPF 15 lotion

SYNONYMS: Oil of Citronella

SPONSOR: Primavera Products, Inc., 950 Third Avenue, New York, NY

STUDY NUMBER: 062861-1

TESTING FACILITY: United States Testing Company, Inc., Biological Services Division, 1415 Park Avenue, Hoboken, NJ

TITLE OF REPORT: Acute Inhalation Toxicity Limit Test - 4 hrs on TREO SPF 15 Lotion

AUTHOR: Charles C. Tong

STUDY COMPLETED: November 19, 1991

CONCLUSIONS: The acute 4-hour inhalation LC_{50} for TREO SPF 15 lotion was greater than 5.45 mg/L, the highest achievable concentration, in male and female rats.

CORE CLASSIFICATION: Core Supplementary. This study did not satisfy the Guideline (81-3 and 152-12) requirements for an acute inhalation study in rats because of several study deficiencies. Particle size analyses were not monitored during the actual exposure period to insure consistency of the aerosol generating system. The purity of the test material and the age of the animals were not reported. Humidity (>95%) exceeded the normal range (40-60%). However, since the test material was diluted 1:1 with water, the humidity would be expected to increase. This study can be upgraded pending submission of the above-referenced information/data.

TOXICITY CATEGORY: IV-Caution

A. MATERIALS

1. Test Material

Test material: TREO SPF 15 lotion
Purity: Not determined
Physical description: Off-white lotion
Lot number: Not reported
Storage conditions: Not reported
Stability: Not determined
Vehicle: Deionized water

2. Controls

Animals: None needed
Test substance: None needed

3. Test Animals

Species: Rats
Strain: Sprague-Dawley
Source: Ace Animals, Boyertown, PA
Sex: Male and female
Numbers: Five/sex
Housing: Wire mesh cages (the number of animals/cage was not specified).
Acclimation: One week
Age: Not reported
Weight: 200-300 g
Feeding: Feed (unspecified commercial rat diet) and water provided ad libitum
Selection: By weight

4. Exposure

Route of administration: Inhalation
Concentration: 5.45 mg/L

B. TEST PERFORMANCE

Inhalation Chamber

The inhalation test was performed using two exposures--a 1-hour and a 4-hour exposure period. Each exposure was conducted in a whole body exposure system. The exposure chamber was a 38-liter all-glass apparatus (see Appendix, CBI Figure 1). Animals were housed in a cylindrical mesh cage placed in the middle of the chamber.

Generation of Test Atmosphere

The system was designed to continuously supply a fresh test atmosphere. Compressed air was delivered to a flow meter and then to a collision nebulizer which generated the aerosol. To prevent clogging of the collision nebulizer, 50% of the test material was diluted with deionized water. The compressor airflow rate into the chamber was 8 L/minute. A vacuum pump set at 15 L/minute provided a slight negative pressure in the exposure chamber. There were approximately 23.7 air changes per hour at 15 L/minute flow rate in the exposure chamber. This high flow rate was

necessary to deliver the 1:1 diluted sample into the system at the desired concentration and in order to prevent clogging of the system.

Concentration and Monitoring

The actual concentration of the test substance of the atmosphere from the breathing zone of the animals was determined to be 5.45 mg/L, the highest achievable concentration. This concentration was determined by measuring the change in conductivity of the aqueous phase of the Impinger Scrubber and then reading the values off a standard curve. The actual concentration was monitored at 0, 72, 132, 192, and 252 minutes. Gravimetric measurement of the sample being delivered into the system was performed twice and determined to be 6.4 mg/L. The temperature in the chamber ranged from 21.5 to 22.5°C. The relative humidity was >95%.

Particle Size Determinations

Particle size was determined using an 8-stage Anderson 2000 particle fractionating sampler. Particle size analyses were not performed during actual exposure, only at calibration. When calibrated with a 1:1 diluted test sample, 93.6% of the aerosol generated were respirable with a mean median diameter of 1.7 micron and geometric standard deviation of 1.6.

C. RESULTS AND STUDY AUTHOR'S CONCLUSIONS

No deaths occurred. All animals appeared normal and gained weight throughout the 14-day observation period. No abnormal necropsy observations were noted. Based on these results, the acute inhalation LC_{50} for TREO SPF 15 lotion in male and female rats was greater than 5.45 mg/L.

D. QUALITY ASSURANCE MEASURE

A signed Quality Assurance Statement was presented, but not dated. A Good Laboratory Practice compliance statement was included.

E. REVIEWERS' COMMENTS

This study was classified as Core Supplementary, according to Guideline Series 81-3 and 152-12 because of the following deficiencies: 1) purity and stability data were not determined, 2) the relative humidity (>95%) was out of range (40-60%); however, since the test material was diluted 1:1 with water, the humidity would be expected to increase, 3) the study author did not report how often temperature and humidity were monitored, 4) particle size sampling was not performed during the exposure period; it was performed during calibration, 5) the study author did not indicate if the rats were caged singly or in groups, and 6) the age of the rats was not reported. This study can be upgraded pending submission of the above-referenced information/data.

The reviewers note that the reason for performing the 1-hour exposure was not stated; it appears to have been run in order to generate the standard curve that was used to determine the actual concentration of the test substance, although this is not certain.

Based on the tentative results, the acute 4-hour inhalation LC_{50} for TREO SPF 15 Lotion in male and female rats was greater than 5.45 mg/L, the highest achievable concentration. The concentration exceeded the limit

dose of 5 mg/L for an acute inhalation study. Based on these results, the Toxicity Category for TREO SPF 15 lotion is IV-Caution.

F. APPENDIX

CBI Figure 1, Schematic of Inhalation Exposure System, p. 14

APPENDIX

OIL OF CITRONELLA 021901

Page 7 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

X FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.